

# **EXHIBIT 9**

**PCT**WORLD INTELLECT  
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INTERNATIONAL APPLICATION PUBLISHED



(51) International Patent Classification 6 :

A61M 5/32

A

WO 9602290A1

(43) International Publication Date: 1 February 1996 (01.02.96)

(21) International Application Number: PCT/DK95/00306

(22) International Filing Date: 14 July 1995 (14.07.95)

(30) Priority Data:

0857/94

19 July 1994 (19.07.94)

DK

(71) Applicant (for all designated States except US): NOVO NORDISK A/S [DK/DK]; Novo Allé, DK-2880 Bagsvaerd (DK).

(72) Inventor; and

(75) Inventor/Applicant (for US only): LAV, Steffen [DK/DK]; 50 Lavendelgangen, Birkevang, DK-2700 Brønshøj (DK).

(74) Common Representative: NOVO NORDISK A/S; Corporate Patents, Hansen, Einar, Tronier, Novo Allé, DK-2880 Bagsvaerd (DK).

(81) Designated States: AM, AU, BB, BG, BR, BY, CA, CN, CZ, EE, FI, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LV, MD, MG, MN, MW, MX, NO, NZ, PL, RO, RU, SD, SG, SI, SK, TJ, TM, TT, UA, UG, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

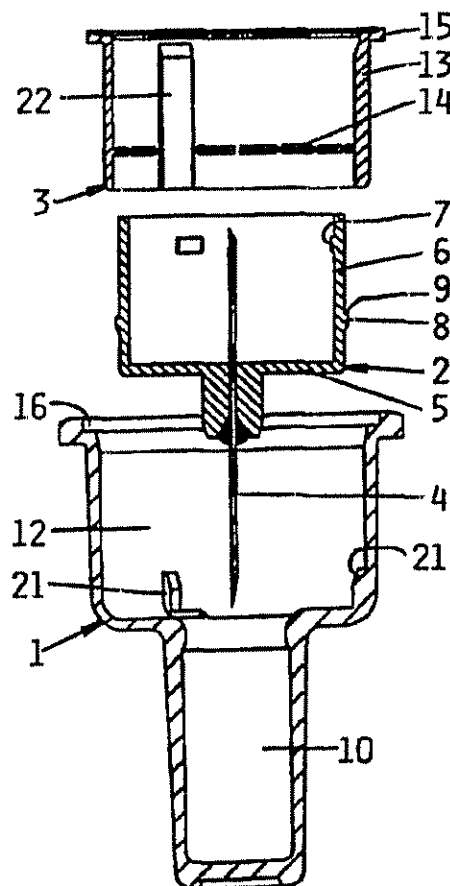
Published

With international search report.

(54) Title: NEEDLE MAGAZINE

## (57) Abstract

A magazine for storing and final disposal of a snap-on needle unit (2) has a compartment (1) having a bottom, a cylindric side wall, and an access opening, which compartment accommodates the needle unit with a gap between the outer side wall of this needle unit and the inner side wall of the compartment. A circle of tongue shaped protrusions (14) are at one end thereof hinged at the inner surface of the side wall of the compartment and are at their other end free. The length of the protrusions exceeds the width of the gap so that the protrusions are deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the needle unit is reinserted in the magazine.



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## NEEDLE MAGAZINE

The invention relates to a magazine for storing and final disposal of a snap-on needle unit carrying a needle mounted in a hub comprising a sleeve with an open end for insertion of a needle receiving part of a syringe and exhibiting a cylindric outer wall.

A snap-on needle unit is a unit which may be mounted on a syringe by an axial movement of the syringe and the needle unit towards each other. During this movement a needle receiving part of the syringe is passed into a sleeve of a needle hub forming part of the needle unit until protrusions on the inner surface of the sleeve engage recesses in the needle receiving part.

In opposition to needle units which are screwed onto the syringe an axial pressure must be exerted on the needle unit and the syringe to provide the snap engagement between the two parts. Correspondingly a certain axial force must be used to pull the syringe and the needle unit apart again when after use the needle is removed from the syringe for final disposal.

During mounting and dismounting of the needle unit it is important that the outer pointed end of the needle is protected so that neither the user nor an assisting person scratch himself by this pointed end. Therefore the needle unit is stored in a magazine which covers the needle unit only leaving free the opening wherein the needle receiving part of the syringe shall be inserted.

It is the object of the invention to provide a magazine which may further be used for removing a used needle from the syringe and for keeping it locked in the magazine in a position so that the used needle may not be removed from the magazine after the reinsertion therein. Further it is the object of the invention to show appropriate modifications of the needle unit design which ensures a good collaboration between the needle unit and the magazine.

A magazine according to the invention is characterized in that it has a compartment having a bottom, a cylindric side wall, and an access opening, which compartment accommodates the needle unit with a gap between the outer side wall

of this needle unit and the inner side wall of the compartment, and that a circle of tongue shaped flexible protrusions at one end thereof are hinged at the inner surface of the side wall of the compartment and at their other end are free, the length of the protrusions exceeding the width of the gap so that the protrusions are  
5 deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the needle unit is reinserted in the magazine.

10 When the needle unit is stored in the magazine the bottom of this magazine supports the needle hub when a needle receiving end of a syringe is pressed into the needle hub to mount this hub onto the syringe. When the needle hub is snap engaged to the syringe it may easily be drawn out of the magazine with the protrusions sliding along the cylindric outer surface of the needle hub. When a used  
15 needle unit is reinserted into the magazine the flexible protrusions will have assumed a position wherein the opening defined by the free end of the protrusion has a smaller diameter than has the cylindric part of the needle hub. When the hub is inserted the protrusions will be deflected with their free ends pointing toward the bottom of the compartment until these protrusions assume an oblique position  
20 where the cylindric part of the needle unit may pass the free ends of the protrusions which may now slide over the surface of the cylindric part during the further insertion of the needle unit into the magazine. When hereafter the syringe is retracted the protrusions will jam in the gap and retain the needle unit back in the magazine so that pulling the syringe and the magazine away from each other will result in a  
25 release of the snap engagement between the needle unit and the syringe.

Not to rely only on the jamming of the protrusions in the gap between the compartment wall and the needle unit the free end of the protrusion abutting the cylindric part of the needle unit may be sharpened so that they will cut into this cylindric part when an attempt is made to move this unit in a direction opposite the  
30 direction indicated by the protrusions.

The circle of sharp ended flexible protrusions may appropriately be provided as radially inward extending tongues in a metal ring fixed to the inner wall of the compartment of the magazine.

Due to the locking function of the protrusions the new needle units which are  
5 sold stored in the magazine may not just be inserted into the magazine as this would put the protrusion in their locking position. Therefore a special packing technique must be used to ensure that the protrusions of magazines with new needle units ready for use are pointing towards the access opening of the magazine. This may be obtained when the protrusions are provided on the inner surface of sleeve which  
10 as a lining is inserted and secured in the compartment. This construction allows that a new and unused needle unit is placed in the magazine whereafter the lining sleeve is inserted in the compartment through the access opening thereof. During the insertion of the lining the free ends of the protrusions will be deflected towards the access opening by the cylindric part of the needle unit already placed in the  
15 magazine. With this direction of the protrusions the needle unit may easily be drawn out of the magazine.

The collaboration of the locking means of the magazine and the cylindric part of the needle unit may be enhanced by appropriate design of said cylindric part. This design may consist in the provision of at least one circumferential edge on the  
20 cylindric wall of the needle unit. The edge may be drawn past the protrusions as long as these protrusions point away from the edge, but a jamming will occur when the ends of the protrusions abuts against the edge as the protrusion not only have to be deflected but must be crumbled to let the edge pass.

Such an edge may be provided by the ends of a number of circumferentially  
25 spaced axial ribs on the cylindric outer wall of the needle unit.

In another embodiment the cylindric part of the needle unit may be provided with a circumferential ring shaped protrusion to provide the circumferential edge.

In still another embodiment the circumferential edge may be provided as the edge of a circumferential recess in the cylindric part of the needle hub.

In the following the invention is further described with reference to the drawings, wherein

- Figure 1 shows a sectional view of a not assembled embodiment of a magazine and needle according to the invention,
- 5 Figure 2 shows a sectional view of the embodiment in figure 1 assembled for storage,
- Figure 3 shows a sectional view of the embodiment in figure 2 with the needle finally disposed of in the magazine,
- 10 Figure 4 shows a sectional view of another embodiment of a magazine with a stored needle unit,
- Figure 5 shows a locking ring for the magazine shown in figure 4, and
- Figure 6 shows an exploded view of an embodiment of a magazine with a needle before assembling.

In figure 1 is shown a magazine 1, a needle unit 2, and a locking sleeve 3 in  
15 a position ready to be assembled to store the needle unit in the magazine in a way making it possible to take the needle unit from the magazine and to reinsert the needle unit in the magazine for final disposal.

The needle unit 2 comprises an injection needle 4 carried in a needle hub comprising a bottom 5 which carries a cylindric sleeve 6 surrounding one end of the  
20 needle 4 and having at its inner surface protrusions 7 for engagement with recesses in a needle receiving part of a syringe. On its outer surface the sleeve 6 has a circumferential rib 8 exhibiting an edge 9 facing the open syringe receiving end of the sleeve.

The magazine 1 comprises a needle accommodating compartment 10, needle hub support ribs 21, and a sleeve accommodating compartment 12. The needle unit 2 is inserted in the magazine 1 with the end of the needle not surrounded by the sleeve 6 inserted in the compartment 10 and the bottom 5 of the needle hub abutting against the needle support ribs 21. Thereby the sleeve 6 will be centered in the compartment 12 leaving a uniform gap between the outer surface of the sleeve 6 and the inner surface of the cylindric wall of the compartment 12 allowing the locking sleeve 3 to be pressed in through an open end of the compartment 12.

The locking sleeve 3 has a cylindric wall 13 which is at its inner surface along a circle in a plane perpendicular to the axis of the sleeve 13 provided with tongue shaped projections 14 which are flexible in their connection to the inner wall of the locking sleeve 13 and which extend radially so that the circle defined by their free ends has a minor diameter than has the needle hub. Consequently, when the locking sleeve 3 is inserted in the gap between the needle hub and the inner wall of the compartment 12 the needle hub will abut the projections 14 and deflect them to adopt an oblique position with their free ends pointing towards the open end of the magazine as shown in figure 2. The locking sleeve 3 is secured in the compartment 12, e.g. by having a flange 15 which is received in a recess 16 surrounding the access opening of the magazine and a gluing or welding being established between the flange 15 and the recess 16. Alternatively an irreversible snap lock connection may be provided between the outer surface of the locking sleeve and the inner cylindric surface of the compartment 12.

When the needle unit 2 is positioned in the magazine 1 and the locking sleeve is inserted in the gap between the needle hub and the magazine the magazine is closed by a membrane 17 covering the access opening of the magazine and the needle unit may in this way be maintained sterile as long as it is stored in the magazine. The membrane may be made from paper which does not allow germs to pass but is permeable to hot steam used to sterilize the needle unit in the magazine.

When the needle unit is going to be used, the membrane 17 is removed and the needle receiving part of a syringe is inserted into the open end of the sleeve 6

and moved into this sleeve until the protrusions 7 engages the recesses in the needle receiving part of the syringe. When the syringe is retracted the needle unit will follow this syringe due to the snap connection between this needle unit and the syringe. The protrusion 8 of the needle hub may pass the tongues of the locking 5 sleeve as these tongues are passed in a direction allowing them to be further deflected. When the needle unit is removed from the magazine the tongues will due to their flexibility return to a position with their free ends defining a circle having a diameter smaller than the diameter of the needle hub.

When after use the needle hub mounted on the syringe is reinserted in the 10 magazine the needle hub will abut the tongues and deflect them to an oblique position with their free ends pointing away from the access opening of the magazine. During further insertion of the needle unit the protrusion 8 of this unit may pass the tongues and after this passing the needle unit is locked in the magazine as a retraction will cause the free ends of the tongues to abut against the edge 9 and 15 consequently the force exerted on the tongues during a retraction of the needle unit is not a deflecting one but a force in the longitudinal direction of the tongues so that the tongues must be crumbled before the needle unit may be removed from the magazine. For such a crumbling a force is needed which far exceeds the force needed to release the snap connection between the needle unit and the syringe, 20 and consequently the needle unit will remain in the magazine when the syringe is retracted.

In the shown embodiment the needle unit was designed for use with the magazine by having an edge 9 facing the access opening of the magazine. This edge 9 is provided on a circumferential protrusion 8 of the needle unit. The edge 25 may alternatively be provided as end surfaces of circumferentially spaced ribs on the outer surface of the sleeve 6 or as an edge of a circumferential recess in this outer surface.

In a more universal embodiment of the magazine no special designed needle unit is demanded. In such an embodiment tongues 14 having a sharp free end are 30 provided as radially inward pointing tongues of metal or a hard plastic. The sleeve

13 and the tongues 14 are preferably moulded as one integral part. However, if different materials are used for the sleeve and the tongues, a flat ring 18 is provided with radial inward pointing tongues 14 as shown in figure 5. This ring has a diameter corresponding to the diameter of the access opening of the magazine. When the 5 needle unit is positioned in the magazine the ring is placed in the gap between the needle unit and the wall of the compartment 12 so that the needle hub deflects the tongues 14 to an oblique position with their free ends abutting the outer surface of the sleeve 6. The ring 18 is placed so it abuts a shoulder formed by ends of the needle hub supporting ribs 21 and is secured in this position by a sleeve 20 inserted 10 from the access opening of the magazine as shown in figure 4. During the first removal and the reinsertion of the needle hub the tongues 14 will function in the same way as the tongues 14 in figure 1 - 3, but if an attempt is made to remove the reinserted needle unit from the magazine the sharp free end of the tongues will cut into the surface of the needle hub and provide a detent against removal of the 15 needle unit. This function is not depending on the needle unit design and the protrusions 8 shown in figure 4 are not actually needed.

Figure 6 shows an exploded view of a magazine with a needle unit. In this figure it is seen that some of the tongues in the locking sleeve are replaced by axial guiding ribs 22 which abutting an outer circumferential surface of the needle unit 20 contribute to the centering of the needle unit in the magazine.

### Claims

1. A magazine for storing and final disposal of a snap-on needle unit carrying a needle mounted in a hub comprising a sleeve with an open end for insertion of a needle receiving part of a syringe and exhibiting a mainly cylindric outer wall, 5 characterized in that the magazine has a compartment having a bottom, a cylindric side wall, and an access opening, which compartment accommodates the needle unit with a gap between the outer side wall of this needle unit and the inner side wall of the compartment, and that a circle of tongue shaped protrusions at one end thereof are hinged at the inner surface of the side wall of the compartment and at 10 their other end are free, the length of the protrusions exceeding the width of the gap so that the protrusions are deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the 15 needle unit is reinserted in the magazine.

2. A magazine according to claim 1, characterized in that the free end of the protrusions abutting the cylindric part of the needle unit are sharpened.

3. A magazine according to claim 2, characterized in that the protrusions are provided as radially inward extending tongues in a metal ring fixed at the inner wall 20 of the compartment of the magazine.

4. A magazine according to anyone of the claims 1 - 3, characterized in that the protrusions are provided on the inner surface of a sleeve which as a lining is inserted and secured in the compartment.

5. A needle hub for use in a magazine according to the claims 1-4, characterized in that on the mainly cylindric outer wall of the needle unit at least one circumferential edge is provided facing the open end of the sleeve.

6. A needle hub according to claim 5, characterized in that the edge is defined by the ends of a number of circumferential spaced axial ribs on the cylindric outer wall of the needle unit.

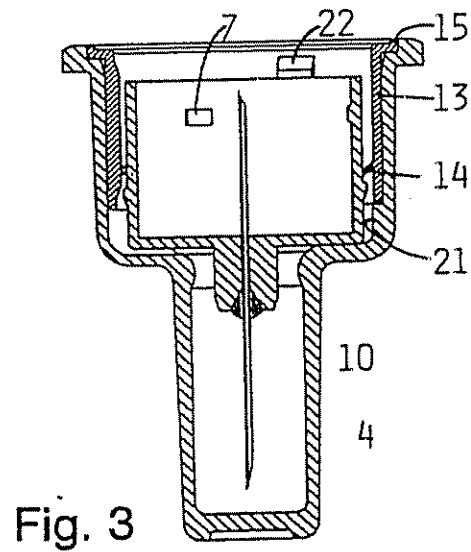
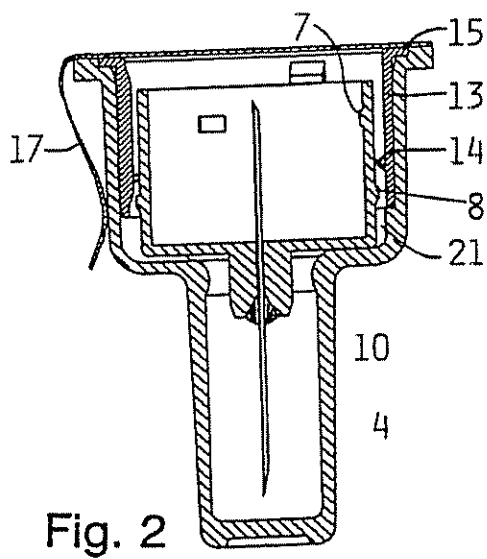
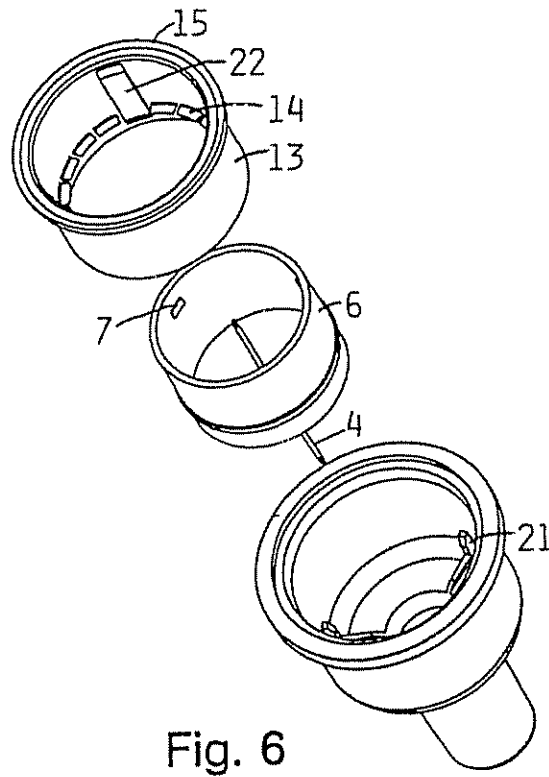
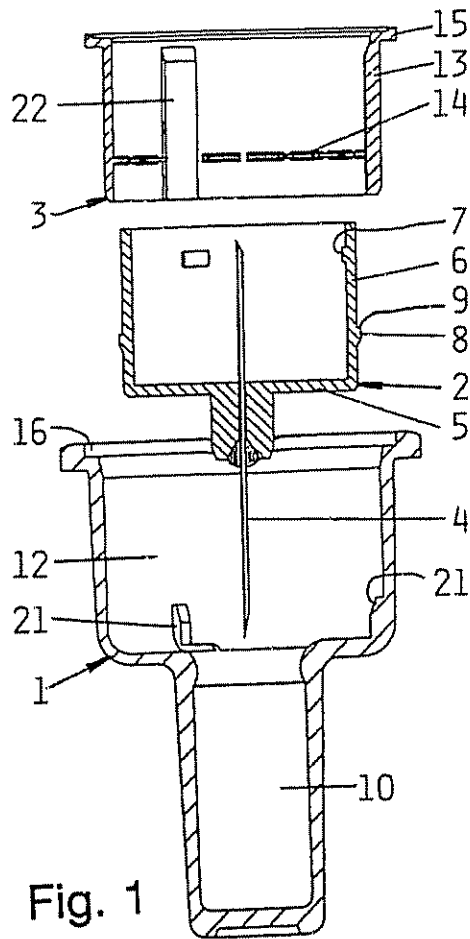
7. A needle hub according to claim 5, characterized in that the edge is provided by the cylindric outer wall of the needle unit being provided with a circumferential ring shaped protrusion.

10 8. A needle hub according to claim 5, characterized in that the edge is provided as an edge of a circumferential recess in the cylindric outer wall of the needle hub.

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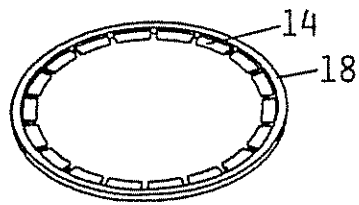
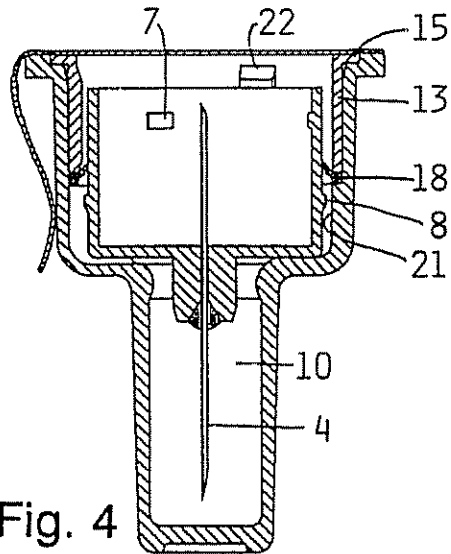
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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 95/00306

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/32

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WD 8200412 A1 (ELISHA, BENJAMIN), 18 February 1982 (18.02.82), page 4, line 18 - line 27, figure 2	1-4
X	figure 3  -----	5,7



Further documents are listed in the continuation of Box C.



See patent family annex.

## \* Special categories of cited documents:

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Date of the actual completion of the international search

10 October 1995

Date of mailing of the international search report

10-11-1995

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Swedish Patent Office  
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Authorized officer

May Hallne  
Telephone No. +46 8 782 25 00



# **EXHIBIT 10**



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Publication number: **0 688 571 A1**

**EUROPEAN PATENT APPLICATION**

Application number: 95303894.0

Int. Cl.<sup>6</sup>: A61M 5/315

Date of filing: 07.06.95

Priority: 22.06.94 US 263591  
28.09.94 US 314179

Date of publication of application:  
27.12.95 Bulletin 95/52

Designated Contracting States:  
DE ES FR GB IT

Applicant: Becton Dickinson and Company  
One Becton Drive  
Franklin Lakes,  
New Jersey 07417-1880 (US)

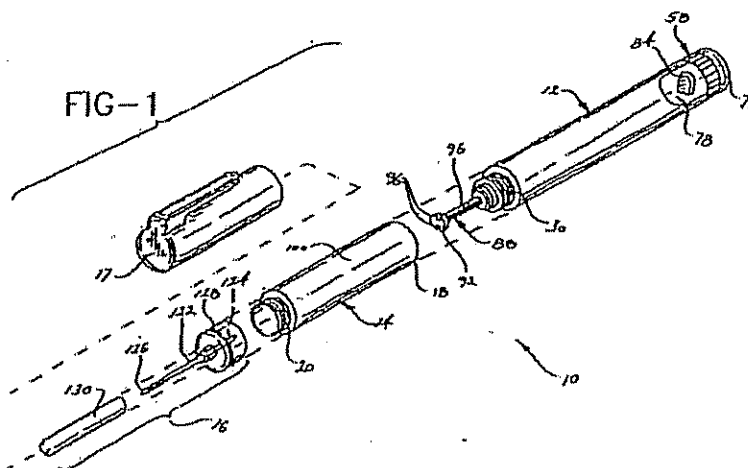
Inventor: Chanoch, Lawrence H.  
153 Fischer Road  
Mahwah,  
New Jersey 07430 (US)  
Inventor: Wilson, John B.  
42 Cannonball Road  
Wanague,  
New Jersey 07465 (US)

Representative: Ruffles, Graham Keith  
MARKS & CLERK,  
57-60 Lincoln's Inn Fields  
London WC2A 3LS (GB)

**Quick connect medication delivery pen**

A medication delivery pen is provided having a reusable pen body assembly and a disposable cartridge assembly that are threadably engageable with one another. The disposable cartridge assembly includes a plunger and can releasably receive a needle cannula assembly. A portion of the pen body assembly projects into the cartridge holder assembly

for driving the cartridge plunger distances that are selected in accordance with a desired dose of medication to be delivered. The cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, and the used cartridge holder assembly may be discarded and replaced.



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**BACKGROUND OF THE INVENTION****1. Field of the Invention**

The subject invention relates to medication delivery pens having a disposable cartridge holder assembly and a reusable pen body assembly removably mounted to the cartridge holder assembly for delivering selected doses of medication.

**2. Description of Related Art**

Hypodermic syringes are used to deliver selected doses of medication to patients. The prior art hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid receiving chamber. The proximal end of the prior art syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the prior art syringe barrel includes a passage communicating with the chamber. A needle cannula may be mounted to the distal end of the prior art syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel. Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

Medication to be injected with the prior art hypodermic syringe often is stored in a vial having a pierceable elastomeric seal. Medication in the prior art vial is accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication may be drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula may be withdrawn from the vial, and the medication may be injected into a patient by moving the plunger in a distal direction.

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the stan-

dard prior art hypodermic syringe and vial can be inconvenient and embarrassing in these public environments.

Medication delivery pens have been developed to facilitate the self-administration of medication. One prior art medication delivery pen includes a vial holder into which a vial of insulin or other medication may be received. The vial holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the prior art vial holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable vial for use with the prior art vial holder includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this prior art vial includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the vial. This prior art medication delivery pen is used by inserting the vial of medication into the vial holder. A prior art pen body then is connected to the proximal end of the vial holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the vial distally for a distance corresponding to the selected dose.

The user of the pen mounts a prior art double-ended needle cannula to the distal end of the vial holder such that the proximal point of the needle cannula pierces the elastomeric seal on the vial. The patient then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The dose selecting apparatus returns to zero upon injection of the selected dose with this prior art medication delivery pen. The patient then removes and discards the needle cannula, and keeps the prior art medication delivery pen in a convenient location for the next required medication administration. The medication in the vial will become exhausted after several such administrations of medication. The patient then separates the vial holder from the pen body. The empty vial may then be removed and discarded. A new vial can be inserted into the vial holder, and the vial holder and pen body can be reassembled and used as explained above.

The above described reusable medication delivery pen is effective and much more convenient for self-administration of medication than the typical hypodermic syringe and separate medication vial. However, the disassembly of the pen to remove empty medication vials and to insert new ones is an inconvenience. As a result, disposable pens have been developed. The prior art disposable medication delivery pen includes a vial of

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insulin or other such medication permanently encapsulated therein. The patient need merely connect a double-ended needle cannula to the disposable pen for each administration of medication. The prior art disposable pen can be discarded when the supply of medication permanently encapsulated therein has been exhausted.

Disposable medication delivery pens offer certain conveniences to the patient who is required to self-administer medication. However, the dose selecting and driving mechanisms of prior art medication delivery pens are fairly complex devices that are costly to manufacture. Hence, a substantial cost penalty is associated with the convenience of using a disposable medication delivery pen.

#### SUMMARY OF THE INVENTION

The subject invention relates to a medication delivery pen having a disposable medication cartridge assembly that is selectively engageable with and disengageable from a reusable pen body assembly. The disposable medication cartridge assembly is an elongate generally cylindrical structure having opposed proximal and distal ends. The distal end of the disposable medication cartridge assembly includes needle mounting means for securely but releasably receiving a needle cannula assembly. The distal end may be characterized by a pierceable elastomeric seal that may be repeatedly and resealably pierced by the proximal end of a double-ended needle cannula. The proximal end of the disposable medication cartridge assembly includes body mounting means for securely but releasably mounting the disposable medication cartridge assembly to the reusable pen body assembly. The body mounting means may comprise an array of threads extending distally from the proximal end of the disposable medication cartridge assembly.

The disposable medication cartridge assembly further includes plunger means slidably disposed in fluid tight engagement therein. The plunger means may initially be disposed in a proximal position within the medication cartridge assembly and may be moved in a distal direction by a driver projecting from the pen body assembly. The disposable medication cartridge assembly further comprise anti-rotation means for preventing rotation of the driver.

The reusable pen body assembly of the subject invention comprises an array of mounting threads to enable threaded engagement of the reusable pen body assembly and the disposable medication cartridge assembly. An actuator button may be rotatably mounted on the proximal end of the pen body assembly. Thus, axial forces exerted on the actuator button will cause the pen body

assembly to threadedly engage the disposable medication cartridge assembly.

The pen body assembly further includes a lead screw for selectively engaging the plunger of the disposable cartridge assembly and for urging the plunger of the disposable cartridge assembly in a distal direction. At least a portion of the lead screw may have driving threads engaged with other portions of the pen body assembly. This threaded engagement may be operative to achieve axial movement of the lead screw in response to axial forces exerted on the rotatable actuator button. The driving threads may define the same pitch and the same direction of generation as the mounting threads of the pen body assembly. As will be explained in greater detail below, this feature of the medication delivery pen facilitates the quick connection of the pen body assembly to the disposable medication cartridge assembly, and further assures a virtually automatic return of the lead screw to a start position each time a new disposable medication cartridge assembly is mounted to the pen body assembly. The lead screw may further be engageable with the anti-rotation means of the disposable cartridge assembly. Thus, relative rotation between the lead screw means and the disposable cartridge assembly is substantially prevented.

The pen body assembly further comprises a dose setting means for establishing and precisely controlling the amount of medication to be delivered in response to each actuation of the actuator button. The dose setting means may be any of several structures as described in greater detail below.

A disposable cartridge assembly that is filled with medication may be mounted to the pen body assembly by merely aligning the lead screw with the proximal end of the disposable cartridge assembly and exerting an axial force on the rotatable actuator button. The initial response to forces on the actuator button will cause the lead screw to move in a proximal direction toward its starting position, while the remaining portions of the pen body assembly move distally toward the disposable vial assembly. Further forces exerted on the actuator button will cause the mounting means of the pen body to engage the mounting means of the disposable cartridge assembly. Continued axial forces on the actuator will cause the mounting threads to engage the disposable cartridge assembly and will continue the proximal movement of the driver. The pen body assembly will be fully but releasably engaged with the disposable cartridge assembly at the same time that the driver is at its proximal extreme position and in condition to begin delivering selected doses of medication from the pen. Doses of medication can be dispensed as

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needed over time. The disposable cartridge assembly can be removed and discarded when the medication therein has been exhausted, and a new disposable medication cartridge assembly may be mounted to the pen body assembly as described above.

#### DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exploded perspective view of the medication delivery pen of the subject invention.

Fig. 2 is an exploded perspective view of the pen body assembly of the medication delivery pen shown in Fig. 1.

Fig. 3 is an end view of the housing of the pen body assembly.

Fig. 4 is a cross-sectional view of the nut taken along line 4-4 in Fig. 2.

Fig. 5 is a cross-sectional view of the insert taken along line 5-5 in Fig. 2.

Fig. 6 is an end elevational view of the cartridge holder assembly.

Fig. 7 is a longitudinal cross-sectional view of the pen in a first partly assembled condition.

Fig. 8 is a cross-sectional view similar to Fig. 7, and showing the pen in a second partly assembled condition.

Fig. 9 is a cross-sectional view similar to Figs. 7 and 8, and showing the pen in a fully assembled condition.

Fig. 10 is a cross-sectional view similar to Fig. 9, and showing the assembled pen in condition to deliver a selected dose of medication.

Fig. 11 is a cross-sectional view similar to Fig. 10 and showing the pen after delivery of the selected dose.

#### DETAILED DESCRIPTION

A medication delivery pen in accordance with the subject invention is identified generally by the numeral 10 in Figs. 1 and 7-11. Medication delivery pen 10 includes a reusable pen body assembly 12, a disposable cartridge assembly 14, a needle cannula assembly 16 and a cap 17. Cartridge assembly 14 includes opposed proximal and distal ends 18 and 20 respectively. Proximal end 18 of cartridge assembly 14 is dimensioned and configured to threadedly engage pen body assembly 12, as explained further herein. Distal end 20 of cartridge assembly 14 is configured to securely but releasably engage needle cannula assembly 16.

The preferred embodiment of reusable pen body assembly 12 is illustrated in greater detail in Fig. 2. It is understood, however, that variations from this preferred embodiment may be provided, and are considered to be within the scope of the subject invention. Reusable pen body assembly 12

includes a generally cylindrical housing 22 having opposed proximal and distal ends 24 and 26, and a substantially hollow throughbore 28 extending axially therethrough. An array of external threads 30 extends proximally from distal end 26 for threaded engagement with proximal end 18 of cartridge holder assembly 14. Portions of hollow throughbore 28 of housing 22 adjacent distal end 26 are characterized by an array of clutch teeth 32, shown in Fig. 3, molded therein. Proximal end 24 of housing 22 is characterized by a cut-out 33 formed therein for receiving a window insert 78, as shown in Fig. 5 and explained further herein.

Pen body assembly 12 further includes a nut 34 having opposed proximal and distal ends 36 and 38 respectively. Exterior surface regions of nut 34 between proximal and distal ends 36 and 38, shown in Fig. 4, define a plurality of longitudinally extending splines 39. Proximal end 36 of nut 34 is characterized by a plurality of longitudinally extending resilient fingers 40 with enlarged ends that enable snap engagement of nut 34 into other portions of pen body assembly 12 as explained further herein. Distal end 38 of nut 34 is radially enlarged to limit axial movement of nut 34 into distal end 26 of housing 22. Thus, nut 34 is axially constrained within housing 22. However, the dimensions and configurations of nut 34 and housing 22 permit free relative rotation therebetween.

Pen body assembly 12 further includes a clutch assembly 42 mounted therein. Clutch assembly 42 includes a proximal clutch 44, a distal clutch 46 and an annular spring 48 biasingly engaged therebetween. Proximal and distal clutches 44 and 46 each are configured for non-rotatable engagement over splines 39 of nut 34. Distal clutch 46 includes an array of distally facing saw teeth dimensioned, disposed and configured for engagement with teeth 32, shown in Fig. 3, on the interior of housing 22, such that distal clutch 46 can rotate only in one direction relative to housing 22. Proximal clutch 44 includes an array of proximally facing teeth which are also configured for unidirectional rotation as explained further herein.

Pen body assembly 12 further includes a generally cylindrical driver 50 having opposed proximal and distal ends 52 and 54. Driver 50 is slidably inserted into housing 22 of pen body assembly 12 such that distal end 54 of driver 50 is snap fit over the enlarged ends of resilient fingers 40 at proximal end 36 of nut 34. This snap fit engagement prevents axial movement between nut 34 and driver 50, but permits free relative rotational movement within housing 22. Distal end 54 of driver 50 is also characterized by an array of saw teeth 49 that engage with the saw teeth on proximal clutch 44. Outer surface regions of driver 50 are characterized by splines 56 extending radially outwardly

thereon and along a substantial portion of the length of driver 50.

Pen body assembly 12 further includes a dose knob 58 which is a hollow generally cylindrical structure having opposed proximal and distal ends 60 and 62 and opposed inner and outer surfaces 64 and 66. Inner surface 64 is characterized by longitudinally extending grooves 68 which are disposed and dimensioned for engagement with splines 56 on driver 50. More particularly, dose knob 58 is spline mounted over driver 50 within housing 22 of pen body assembly 12. Thus, axially extending grooves 68 in dose knob 58 engage splines 56 of driver 50 to prevent relative rotation therebetween, but permitting relative axial movement. Outer surface 66 of dose knob 58 is characterized by a groove 70 that includes a linear component 72 and a helical component 74, which connects opposed ends of linear component 72. Portions of outer surface 66 adjacent helical component 74 of groove 70 are provided with dosage indicia to define dose amounts corresponding to different positions along groove 70 as explained further herein. Proximal end 60 of dose knob 58 is characterized by a gnarled exterior surface to facilitate manipulation for setting a selected dose. An actuator button 76 is snapped in to engagement with proximal end 60 of dose knob 58 to permit relative rotation therebetween.

An Insert 78, shown in Figs. 2 and 5, is snapped into engagement with cut-out 33 in the proximal end 24 of housing 22. Insert 78 includes opposed inner and outer surfaces 80 and 82 and a window 84 extending therebetween. Inner surface 80 of insert 78 includes a button 86 on an interior face which is dimensioned and disposed to engage in groove 70 of dose knob 58. Button 86 and window 84 are disposed to enable the indicia on dose knob 58 to be visible through window 84.

Pen body assembly 12 further includes a lead screw 88 with opposed proximal and distal ends 90 and 92 and an array of external threads 94. External threads 94 are characterized, however, by a pair of opposed axially extending grooves 96 which extend from distal end 92 substantially to the proximal end 90. Threads 94 are engaged in nut 34, such that proximal end 90 of lead screw 88 is within housing 22 and distal end 92 projects distally beyond housing 22. Threads 94 on lead screw 88 have exactly the same pitch and the same hand as threads 30 on distal end 26 of housing 22.

Pen body assembly 12 is assembled by placing nut 34 into housing 22 from distal end 26. Clutch assembly 42 then is mounted over splines 39 on nut 34. Driver 50 is then inserted into proximal end 24 of housing 22, and is urged sufficiently in a distal direction for snap fit engagement with nut 34. In this snapped engagement, the saw teeth

of distal clutch 46 will be secured in engagement with teeth 32 of housing 22, and the saw teeth of proximal clutch 44 will be engaged with saw teeth 49 at distal end 54 of driver 50. Spring 48 will maintain constant selected pressure between these interengaged saw teeth. Insert 78 then is positioned over dose knob 58 such that button 86 of insert 78 is engaged in the axial return track 72 of groove 70 in dose knob 58. The temporarily assembled insert 78 and dose knob 58 then are urged into housing 22. Lead screw 88 then is threaded into nut 34, and actuator button 76 is snapped into engagement with proximal end 60 of dose knob 58.

Cartridge assembly 14, shown in Figs. 1 and 6-11, includes a molded housing 100 which extends from proximal end 18 to distal end 20 of cartridge assembly 14, as noted above. Housing 100 includes a mounting cavity 102 extending inwardly from proximal end 18. Mounting cavity 102 is characterized by an array of internal threads 104 for threaded engagement with external threads 30 on distal end 26 of housing 22. The distal end of mounting cavity 102 is defined by anti-rotation tabs 106 which are dimensioned to slidably engage in slots 96 of lead screw 88. Thus, lead screw 88 can slidably move relative to anti-rotation tabs 106, but is prevented from rotating relative to tabs 106.

Cartridge holder assembly 14, as shown in Figs. 7-11, further includes a medication cartridge 108 securely retained in housing 100 between tabs 106 and distal end 20 of cartridge assembly 14. Medication cartridge 108 includes an open proximal end 110 and a distal end 112 having a pierceable elastomeric seal 114 securely mounted thereto. A cap 116 extends between housing 100 and cartridge 108 for securely and permanently holding medication cartridge 108 in housing 100. A plunger 118 is disposed in sliding fluid tight engagement in cartridge 108. As shown in Figs. 7-11, plunger 118 initially is disposed substantially adjacent proximal end 110 of medication cartridge 108. Portions of cartridge 108 between plunger 118 and seal 114 are filled with a medication 120, such as insulin.

Needle cannula assembly 16 includes a double ended needle cannula 122 having opposed proximal and distal points 124 and 126, respectively, and a lumen extending axially therebetween. A mounting hub 128 is engaged on needle cannula 122 and is removably engageable with cap 116 of cartridge holder assembly 14. The relative location of mounting hub 128 ensures that proximal point 124 of needle cannula 122 will pierce seal 114 when mounting hub 128 is engaged with cap 116. Needle cannula assembly 16 further includes a shield 130 removably mounted thereon for protecting against accidental needle sticks until immediately prior to use of pen 10.

As noted above, pen body assembly 12 is reusable, and cartridge holder assembly 14 is disposable. More particularly, cartridge 108 in cartridge holder assembly 14 will contain a volume of medication 120 sufficient for administration of several doses. After exhaustion of the medication 120, cartridge holder assembly 14 will be threadedly disengaged from pen body assembly 12 and discarded. A new cartridge holder assembly 14 may then be mounted to the reusable pen body assembly 12. To effect the mounting of a new cartridge holder assembly 14 to the reusable pen body assembly 12, the patient need merely align slots 96 at distal end 92 of lead screw 88 with tabs 106 at proximal end 18 of cartridge holder assembly 14. Distal end 92 of lead screw 88 is then advanced distally into cartridge holder assembly 14 until distal end 92 of lead screw 88 engages plunger 118, as shown in Fig. 7. Assembly continues by merely exerting axial forces on thumb swivel 76 and on cartridge holder assembly 14. Additionally, friction between plunger 118 and cartridge 108 and fluid forces exerted by medication 120 and seal 114 will prevent axial advancement of lead screw 88 beyond the position depicted in Fig. 9 during assembly. Additionally, the splined engagement of distal clutch 46 with nut 34 and the engagement of the teeth on distal clutch 46 with the corresponding teeth 32 on housing 22 prevents independent rotation of nut 34 during this initial mounting of reusable pen body assembly 12 with a new disposable cartridge assembly 14. Thus, axial forces exerted on thumb swivel 76 will cause cartridge housing 100 to threadedly advance along threads 94 of lead screw 88.

After sufficient axial advancement, threads 30 at distal end 26 of pen body housing 22 will engage internal threads 104 at proximal end 18 of cartridge holder assembly 14, as shown in Fig. 8. As noted above, external threads 30 at distal end 26 of housing 22 have exactly the same pitch and hand as threads 94 on lead screw 88. Hence, further axial forces exerted on thumb swivel 76 will cause the simultaneous threaded advancement of housing 22 along lead screw 88 and into cavity 102 at proximal end 18 of cartridge holder assembly 14. Thus, because of their identical pitches, lead screw 88 will move proximally relative to pen body housing 22, while pen body housing 22 and cartridge holder assembly 14 are approaching their fully seated and threaded condition depicted in Fig. 9.

The assembled reusable pen body assembly 12 and cartridge assembly 14 may be stored until a selected dose of medication is required. Just prior to use, a needle cannula assembly 16 may be threadedly engaged to distal end 20 of cartridge assembly 14. This threaded engagement will cause

proximal tip 124 of needle cannula 122 to pierce seal 114 and provide communication with medication 120. Shield 130 may then be removed.

A desired dose of medication 120 may be set by rotating dose knob 58 until indicia corresponding to the desired dose appears in window 84 of insert 78. The engagement of button 56 on insert 78 in helical portion 74 of groove 70 in dose knob 58 will cause a threaded retraction of dose knob 58 relative to housing 22 of reusable pen body assembly 12. This threaded retraction of dose knob 58 will cause a simultaneous rotation of driver 50 splined thereto. However, nut 34 will not rotate because the saw teeth on distal clutch 46 and saw teeth 32 on interior portions of housing 22 are locked to prevent rotation in that direction. Proximal clutch 44 is splined to nut 34, and hence also will not turn. However, saw teeth 49 at distal end 54 of driver 50 are shaped to allow rotation relative to proximal clutch 44, but provide an audible click for each unit of medication in the selected dose. This is helpful for visually impaired patients who may be required to set doses and administer insulin or other medication to themselves. Annular spring 48 contributes to the engagement that provides these audible clicking sounds.

When the desired dose is set, as shown in Fig. 10, injection is achieved by merely pushing on actuator button 76. This causes dose knob 58 to turn about helix 74 relative to pen body housing 22, and driver 50 rotates through the same number of degrees. This rotation is opposite to the rotation generated by the dose setting procedure, and the rotational freedom of the clutch assembly 42 is reversed. Thus, as driver 50 turns the previously clicking proximal clutch 44 is locked to and turns with driver 50. This driving movement of proximal clutch 44 causes a corresponding rotational movement of nut 34 because of the splined engagement therebetween. Distal clutch 46 is now free to rotate against saw teeth 32 on housing 22, and makes an audible clicking indication during injection of medication.

Rotation of lead screw 88 is prevented by tabs 106 unitarily molded with housing 100 of cartridge holder assembly 14. Therefore, as nut 34 rotates under the driving action of proximal clutch 44 and driver 50, lead screw 88 will be advanced axially into cartridge holder assembly 14. This axial advancement of lead screw 88 causes distal end 92 thereof to urge plunger 118 distally into cartridge 108, and hence causes medication 120 to be injected through needle cannula 122. Injection will be terminated when proximal end 60 of dose knob 58 engages against proximal end 24 of pen body housing 22, as shown in Fig. 11.

Upon completion of the injection, needle cannula assembly 16 may be disengaged from car-

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tridge holder assembly 14 and safely discarded. Cap 17 may be mounted over cartridge holder assembly 14, and pen 10 may be stored or carried in a convenient location until the next dose of medication is required. A subsequent dose of medication will be set in exactly the manner as described above. However, for such a subsequent dose, lead screw 88 and plunger 118 will be in a partly advanced position as a starting point. Dose setting and injections can be carried out until all of medication 120 has been used. Cartridge holder assembly 14 may then be threadedly disengaged from pen body assembly 12, and slidably separated from lead screw 88. The separated cartridge holder assembly may then be discarded and replaced as described above.

While the invention has been described with respect to a preferred embodiment, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims. In particular, the reusable pen body assembly may have other driving and/or clutch mechanisms. Additionally, different means for preventing and/or enabling rotation during the dose setting and injection phases may be provided. Similarly, other means for mounting needle cannula to the cartridge assembly may be provided. These various optional constructions will be apparent to those skilled in the art after having read the subject disclosure.

#### Claims

1. A medication delivery pen comprising:

a disposable medication-containing cartridge having a pierceably sealed distal end and an open proximal end having an array of threads, a plunger in sliding fluid tight engagement within said cartridge at a location distally of said array of threads;

a reusable pen body assembly having a housing with opposed proximal and distal ends, said distal end having an array of threads dimensioned and pitched for threaded engagement with said threads at said proximal end of said cartridge, a lead screw having a proximal end disposed in said housing, a distal end projecting beyond said distal end of said housing for selective engagement with said plunger, and threads extending between said proximal and distal ends of said lead screw and defining a pitch substantially equal to said pitch of said threads at said distal end of said pen body assembly, said pen body assembly further comprising driver means for moving said lead screw distally in said pen body assembly selected amounts, whereby said lead screw is movable in a proximal direction in

said pen body assembly as said pen body assembly is threadedly moved in a distal direction into engagement with said cartridge.

2. The medication delivery pen of Claim 1, wherein said pen body assembly further includes an actuator button rotatably mounted on said driver means, such that axial forces exerted on said actuator button simultaneously generate movement of said lead screw in a proximal direction in said pen body assembly and threaded engagement of said pen body assembly distally into said cartridge.

3. The medication delivery pen of Claim 1, wherein said lead screw includes at least one anti-rotation groove extending axially therealong, said cartridge including tab means for slidably engaging in said anti-rotation groove of said lead screw for preventing relative rotation between said lead screw and said cartridge.

4. The medication delivery pen of Claim 3, wherein said cartridge includes a housing unitarily molded from a plastic material, said tab being a unitary portion of said housing.

5. The medication delivery pen of Claim 1, wherein said cartridge defines a mounting cavity adjacent said proximal end thereof, said threads of said cartridge defining internal threads in said mounting cavity, said distal end of said pen body assembly being dimensioned for threaded engagement in said mounting cavity of said cartridge.

6. The medication delivery pen of Claim 1, wherein said pen body assembly comprises dose setting means for defining specified distances of travel for said lead screw corresponding to selected doses of medication to be delivered.

7. The medication delivery pen of Claim 1, wherein said sealed end of said cartridge comprises a pierceable elastomeric seal, and wherein said cartridge further comprises needle mounting means adjacent said distal end of said cartridge, said medication delivery pen further comprising a needle cannula assembly having a hub selectively engageable with the mounting means of said cartridge and a double-ended needle having opposed proximal and distal points, said proximal point of said needle being dimensioned and disposed to pierce said seal upon engagement with said cartridge.

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8. A reusable medication delivery pen system comprising:

a plurality of disposable cartridge holder assemblies, each said disposable cartridge holder assembly including an elongate cartridge housing having opposed proximal and distal ends, an elongate medication-containing cartridge mounted in said cartridge housing, said cartridge having a sealed distal end and an open proximal end, a plunger slidably disposed in fluid tight engagement in said cartridge, medication disposed in said cartridge intermediate said plunger and said seal, said proximal end of said housing of said cartridge holder assembly defining an array of threads;

a reusable pen body assembly having a pen body housing with opposed proximal and distal ends, said distal end of said pen body housing having an array of threads defining a pitch for threaded engagement with said threads at said proximal end of any of said cartridge housing, said pen body assembly having a driver selectively movable in proximal and distal directions in said pen body housing and dose setting means selectively adjustable for controlling amounts of movement of said driver, a lead screw having opposed proximal and distal ends, said distal end of said lead screw being selectively engageable with the plunger of any of said cartridge holder assemblies, said lead screw further comprising an array of external threads thereon threadably engaged for rotation in said body housing, said threads on said lead screw defining a pitch substantially identical to said pitch of said threads on said distal end of said pen body housing, said lead screw being axially movable in said pen body housing in response to movement of said driver for selectively advancing said lead screw distances from said housing corresponding to selected doses of medication, whereby the substantially identical pitches of said threads on said lead screw and on said pen body housing enables said lead screw to move proximally in said body housing simultaneously with threaded engagement of said body housing with said cartridge holder housing.

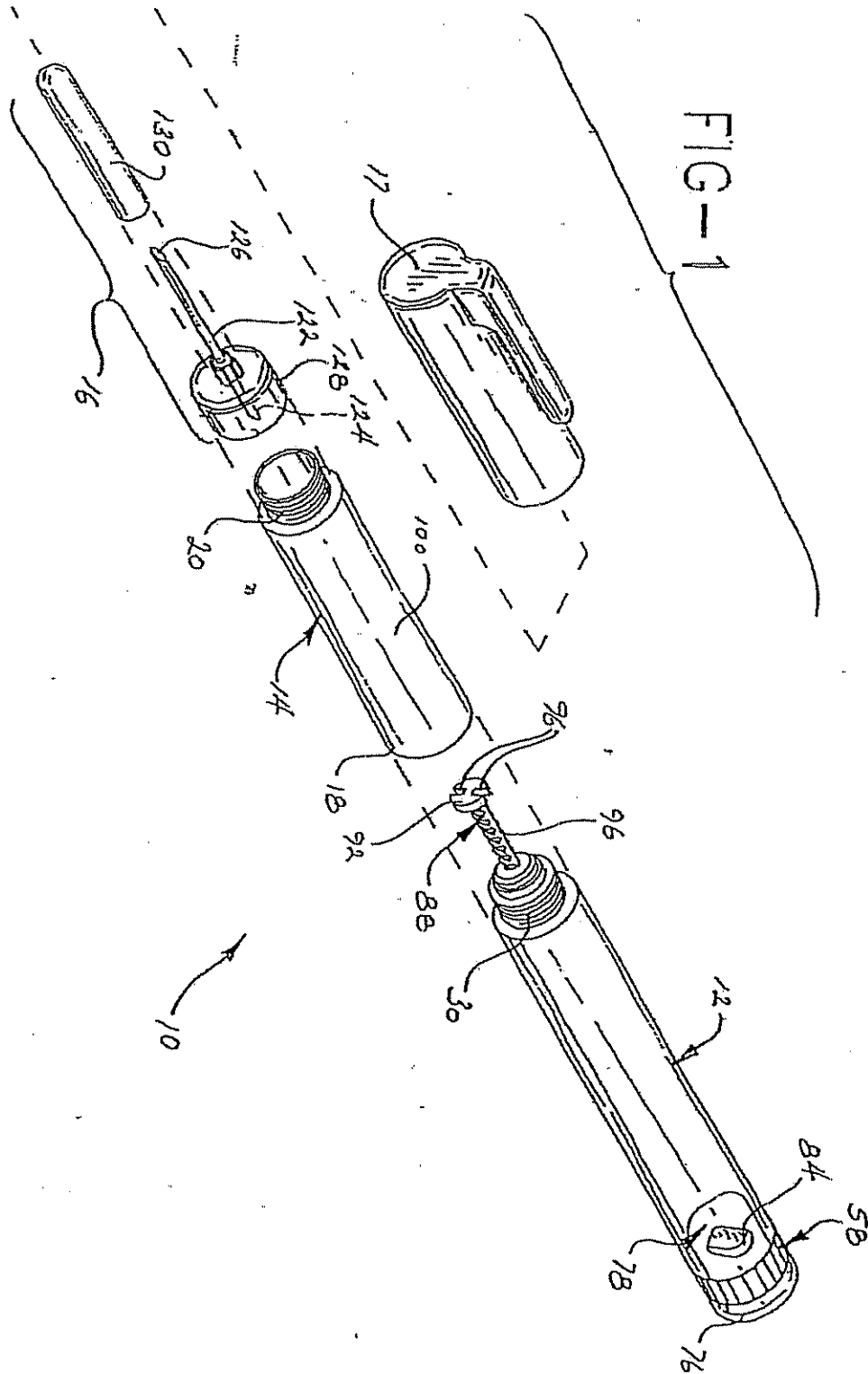
body assembly includes a longitudinally extending groove therein, and wherein each said cartridge housing includes a tab for slidably engaging the lead screw, whereby said tabs prevent relative rotation between said lead screw and said cartridge holder assembly.

9. The medication delivery pen system of Claim 8, further comprising a plurality of needle cannula assemblies, each said needle cannula assembly being selectively engageable and disengageable from each of said respective cartridge holder assemblies.

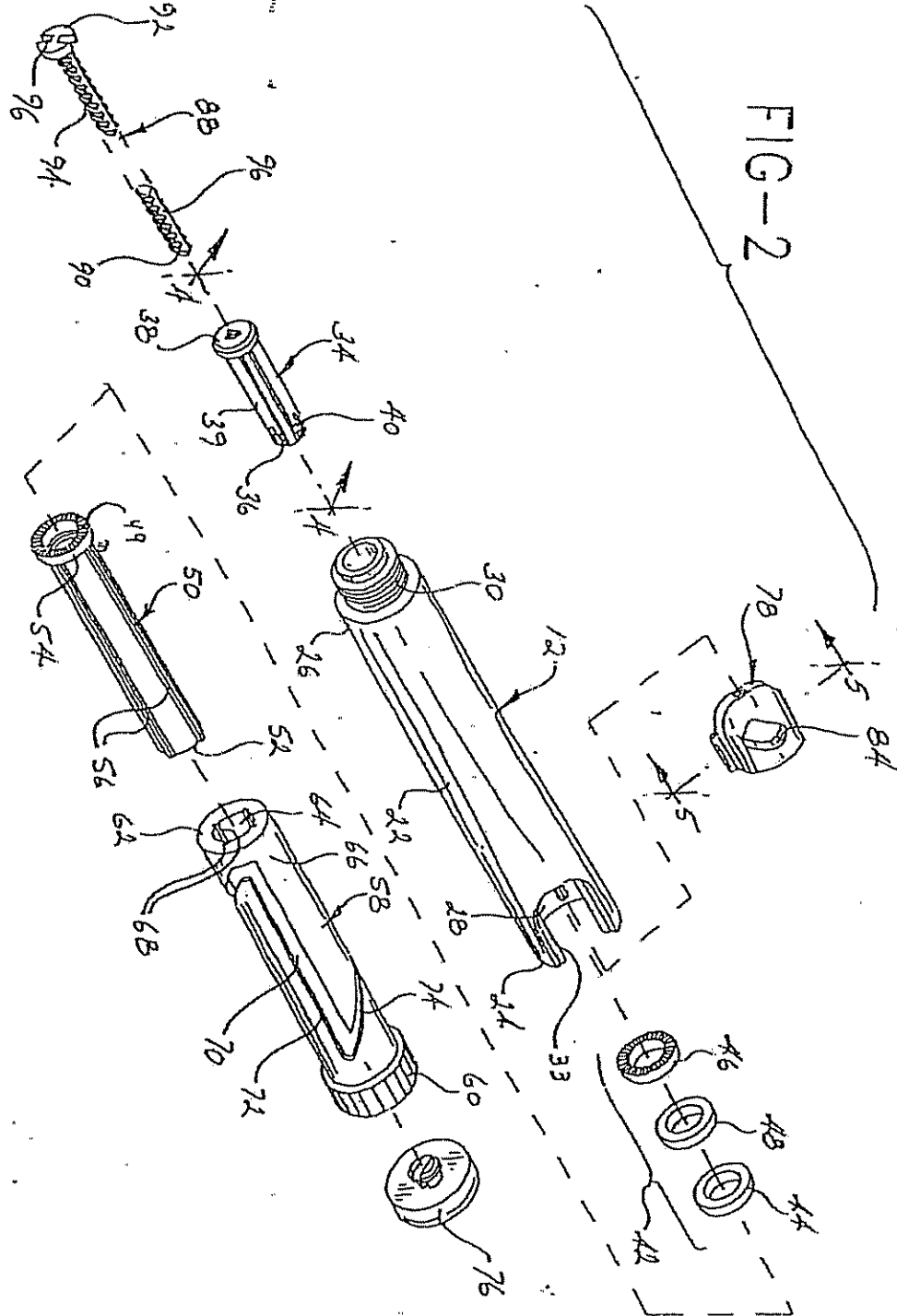
10. The medication delivery pen system of Claim 8, wherein the lead screw of said reusable pen

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FIG-1



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FIG-3

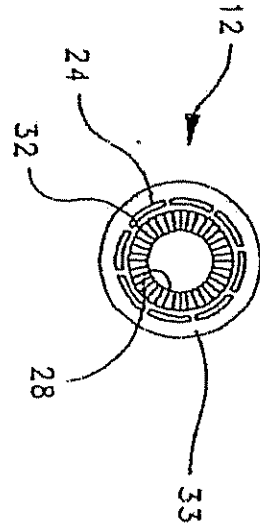


FIG-4

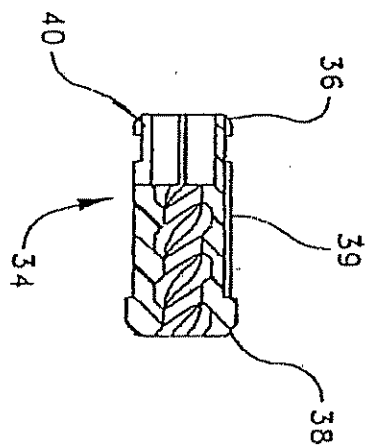


FIG-5

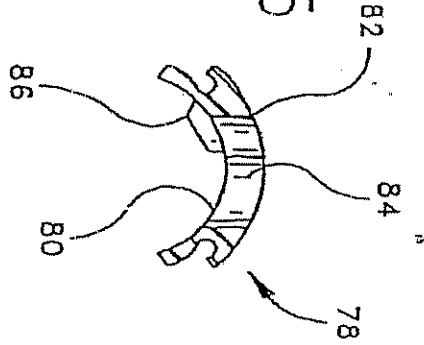
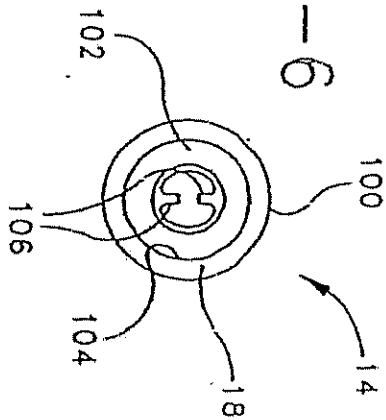


FIG-6



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FIG-7

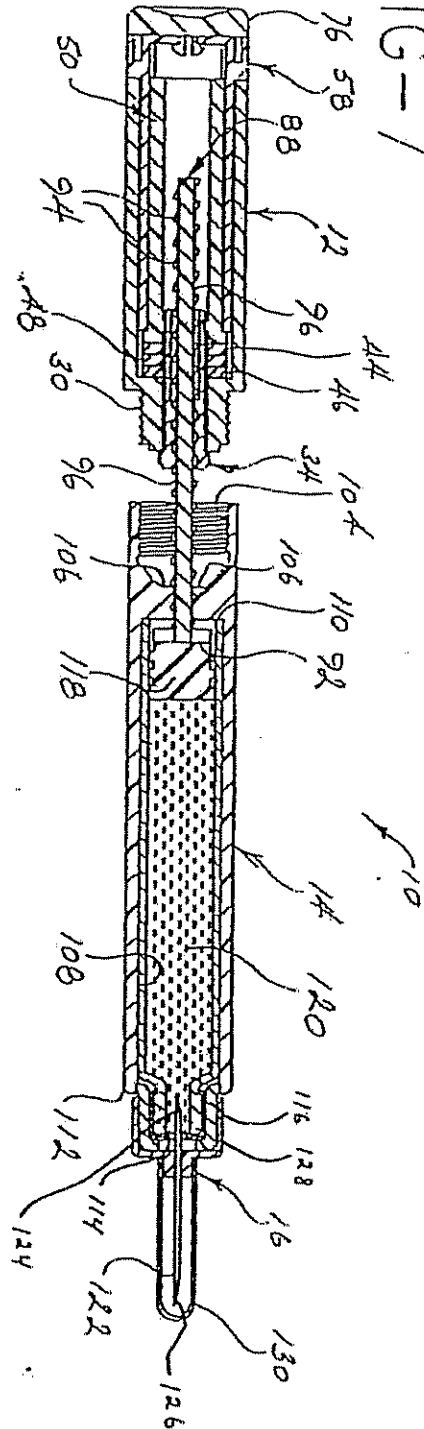
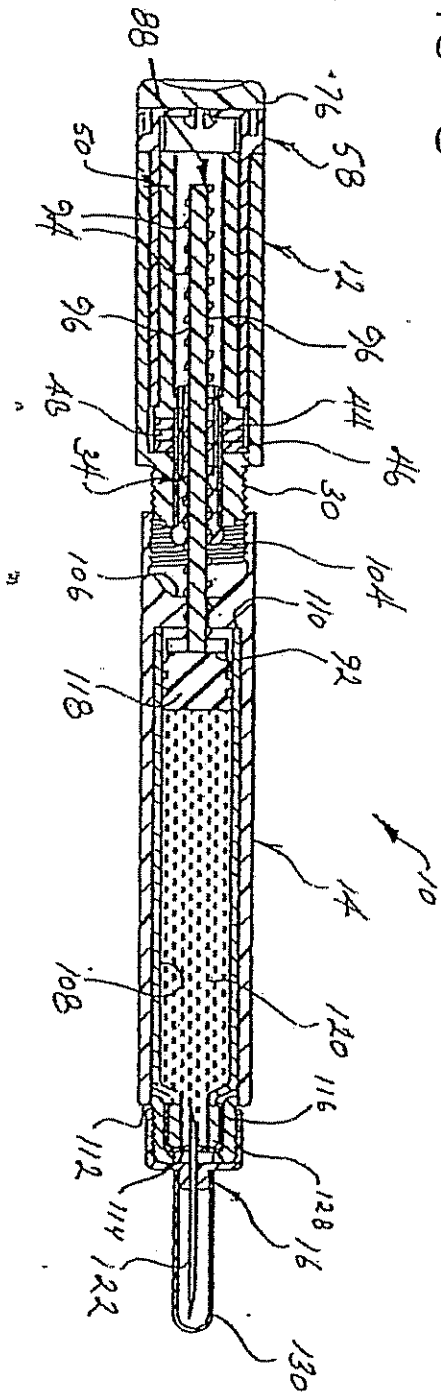


FIG-8



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FIG-9

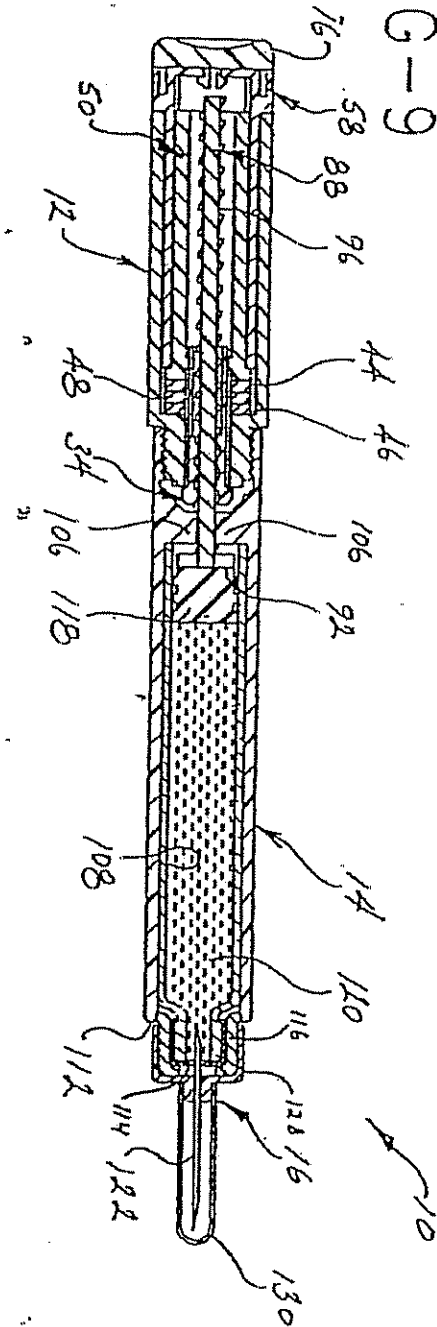
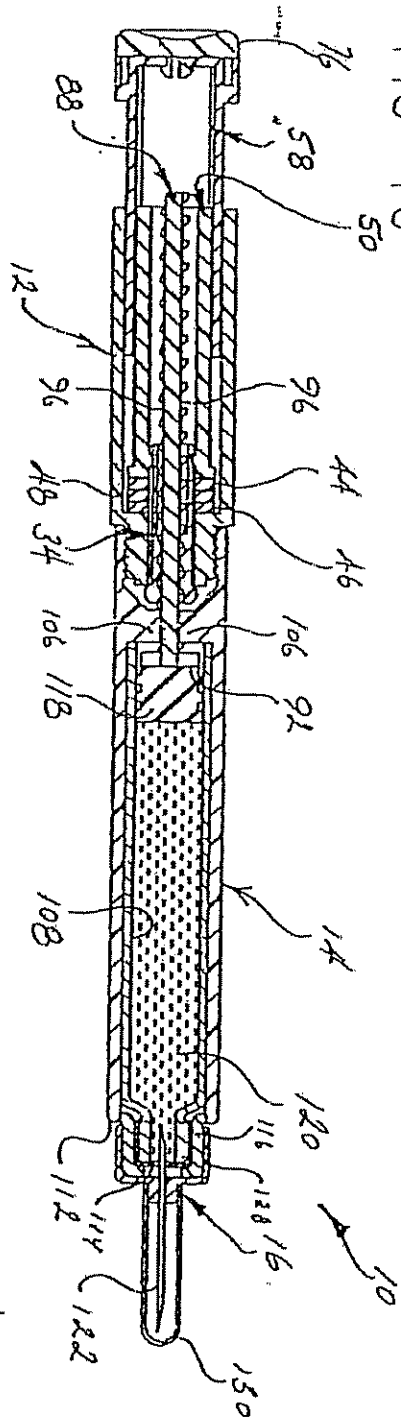
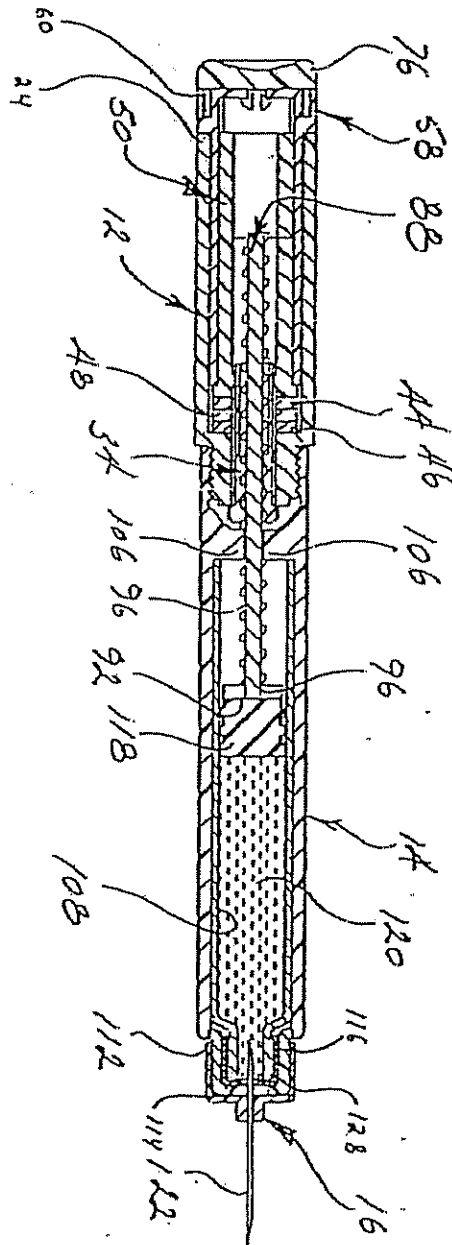


FIG-10



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FIG-11



**EXHIBITS 11 - 15  
REDACTED**

# **EXHIBIT 16**

(12) **United States Patent**  
**Buch-Rasmussen et al.**

(10) **Patent No.:** **US 6,562,011 B1**  
(45) **Date of Patent:** **May 13, 2003**

(54) **MEDICATION DELIVERY DEVICE**

(75) Inventors: Thomas Buch-Rasmussen, Gentofte (DK); Benny Munk, Hvidovre (DK); Jens Ulrik Poulsen, Virum (DK); Henrik Ljunggreen, Ballerup (DK); Peter Møller Jensen, Hørsholm (DK); Jens Møller Jensen, Copenhagen (DK)

(73) Assignee: Novo Nordisk A/S, Bagsvaerd (DK)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/348,536

(22) Filed: Jul. 7, 1999

**Related U.S. Application Data**

(60) Provisional application No. 60/098,702, filed on Sep. 1, 1998.

(30) **Foreign Application Priority Data**

Jul. 8, 1998 (DK) ..... 1998 00909  
Nov. 17, 1998 (DK) ..... 1998 01500

(51) Int. Cl.<sup>7</sup> ..... A61M 5/00

(52) U.S. Cl. .... 604/232

(58) Field of Search ..... 604/200-201,  
604/228, 232-234

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*Primary Examiner*—Brian L. Casler

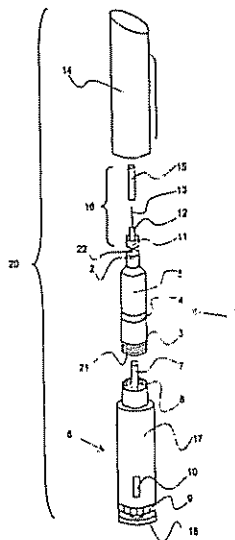
*Assistant Examiner*—Kevin C. Sirmons

(74) *Attorney, Agent, or Firm*—Marc A. Began, Esq.; Richard W. Bork, Esq.; Reza Green, Esq.

(57) **ABSTRACT**

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. At least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The coupling means may be selected from threaded locks, snap locks, hinged locks, or bajonet locks. The medication delivery device is especially suitable for delivering insulin, growth hormone or other medicines.

**7 Claims, 2 Drawing Sheets**



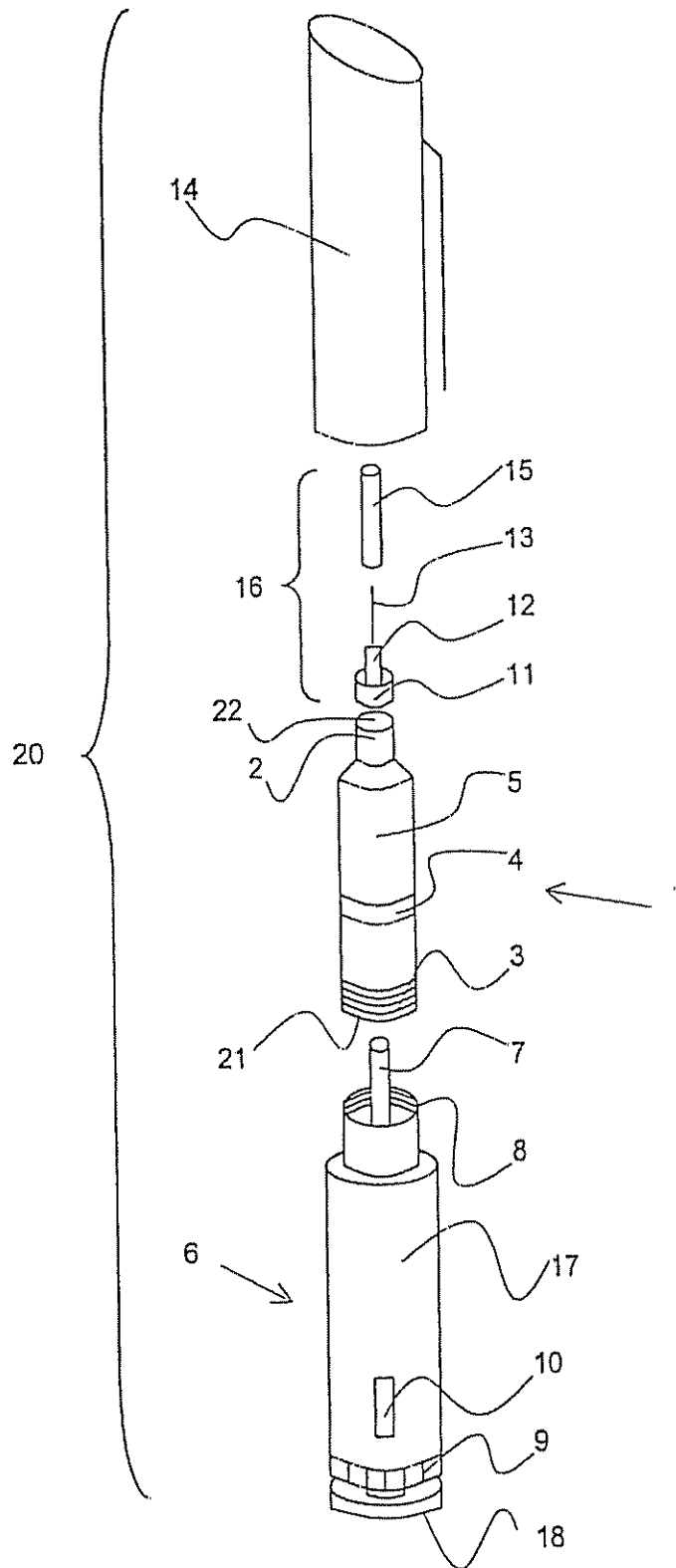


Fig. 1

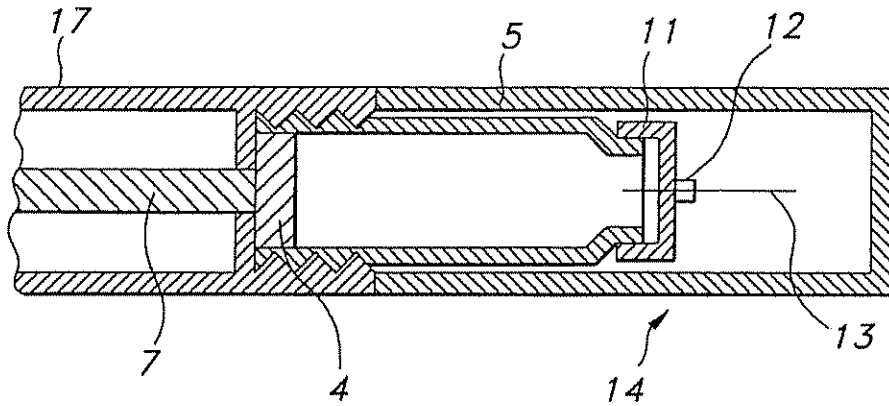


FIG. 2A

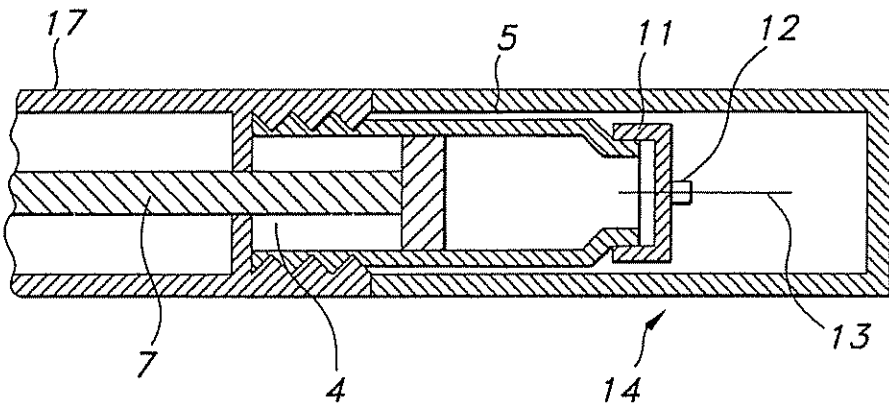


FIG. 2B

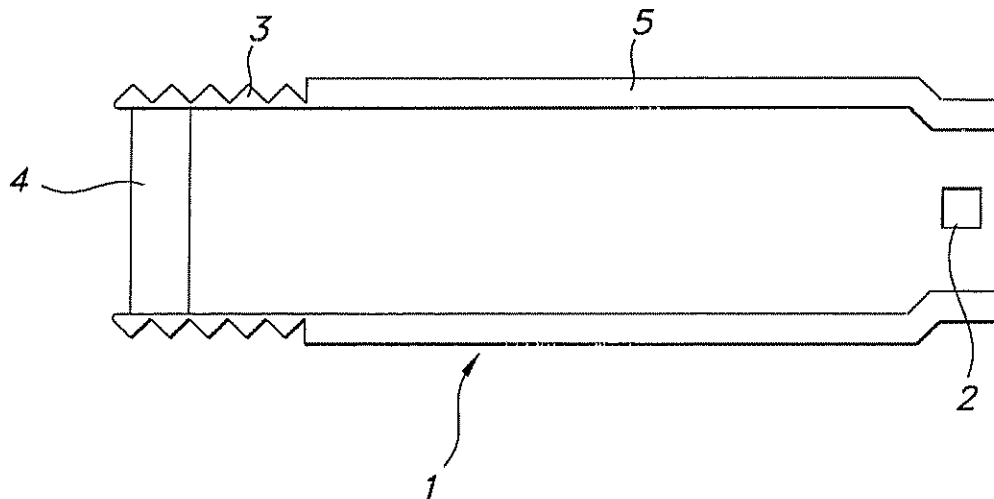


FIG. 3

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**MEDICATION DELIVERY DEVICE****CROSS-REFERENCE TO RELATED APPLICATIONS**

This application claims priority under 35 U.S.C. 119 of Danish application nos. PA 1998 00909 filed Jul. 8, 1998 and PA 1998 01500 filed Nov. 17, 1998, and U.S. provisional application No. 60/098,702 filed Sep. 1, 1998, the contents of which are fully incorporated herein by reference.

The present invention relates to a medication delivery device having a cartridge and a dosing assembly coupled together for delivering selected doses of medication, wherein at least one of the coupling means of the cartridge is unitarily moulded with the cartridge.

**BACKGROUND**

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be replaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

More recent developments have revealed medication delivery pens, wherein the cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced by a new medicine-containing cartridge assembly.

An example of this is shown in EP 0 688 571 disclosing a medication delivery pen having a reusable pen body assembly and a disposable cartridge assembly that are threadably engageable with one another. The cartridge assembly comprises a cartridge, a cartridge housing, a cap between the distal end of the cartridge and the housing, securing the cartridge in the housing and being adapted for engagement with a needle assembly. Furthermore, the cartridge comprises a plunger within the cartridge. The reusable pen body assembly is coupled through a threaded coupling to the cartridge housing. Thus, the total number of parts comprising the prior art cartridge assembly is high.

It is an object of the present invention to provide a medication delivery device wherein the amount of parts of the cartridge is minimized.

**SUMMARY OF THE INVENTION**

Accordingly, the present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly

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comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means has coupling means for engaging the cartridge assembly, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

The unitarily moulded coupling or coupling ensure that the coupling is not accidentally released from the cartridge during use and storage. Also, the above-described medication delivery device has fewer parts than the prior art devices because at least one coupling means is moulded unitarily with the cartridge. Thereby the costs involved in the production and assembling of the device are reduced, and the device is more economical, which is an important feature for a disposable device.

The medical delivering device may either be manufactured as a disposable device which is sold pre-filled with the insulin or it may appear as a durable medical delivering device so designed that it can receive disposable cartridges with insulin.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

The medication delivery device is preferably constructed so as to ensure that the plunger means abuts on the stopper during use of the device, such as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from a reusable dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

A second aspect of the present invention is a cartridge assembly for use in a medication delivery device, said

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cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

The cartridge assembly may further comprise a cartridge housing for protecting the cartridge in use. Furthermore, when the cartridge is moulded unitarily with one coupling means the cartridge housing may comprise the other coupling means. Accordingly, in one embodiment of the invention the housing of the cartridge assembly comprises coupling means for coupling the cartridge assembly to the dosing assembly, preferably the coupling means is moulded unitarily with the housing. The cartridge is arranged within the cartridge housing. The cartridge housing may be non-releasably attached to the cartridge, once the cartridge is arranged in the housing, whereby the housing is disposed with the cartridge. In another embodiment the housing is reusable and the cartridge is arranged releasably in the housing.

In a preferred embodiment all the coupling means of the cartridge assembly are unitarily moulded with the cartridge. Thereby, it is possible to construct the cartridge assembly without the housing providing a cartridge assembly with even fewer parts.

The coupling means of the cartridge assembly may be for any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

The coupling means unitarily moulded with the cartridge are preferably external coupling means, such as an external threaded coupling.

In particular the coupling means for engaging to the dosing means may be an external threaded coupling.

The cartridge may be moulded from any material suitable for medical containers. The cartridge is preferably moulded from a plastic material, e.g. by injection moulding. A suitable choice of material allows the cartridge to be at least partly transparent, whereby the user can see whether content, such as liquid is left in the cartridge. In a preferred embodiment the cartridge is totally transparent giving the user a greater possibility of inspecting the content of the cartridge.

By using a plastic material as compared to the usual glass material a great advantage is achieved in the production lines. Normally a significant quantity of the produced glass cartridges will be spoiled in the lines due to breakage, however the loss is greatly reduced by the use of plastic cartridges. Furthermore, the risk of small loose glass particles in the cartridges have been eliminated.

Also, by moulding the coupling(s) unitarily with the cartridge a very precise coupling mechanism may be obtained, since no further steps are to be taken to attach coupling means to the cartridge.

The cartridge may be of any suitable form, such as a cylinder. The cylinder may be constructed with various combinations of circular or non-circular inner and outer cross-section. In another embodiment the cartridge may be box-shaped having essentially rectangular or triangular cross-section.

The stopper is in sliding fluid tight engagement in the cartridge. The stopper is preferably made of plastic and/or rubber material.

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The flexibility of the cartridge wall is not critical, however if the cartridge is too flexible the function of the stopper may be impaired. Mostly, the cartridge is made of a material only slightly flexible to non-flexible.

In order to enforce and strengthen the cartridge wall the cartridge may be integrally moulded with reinforcements. Thereby, the necessity of a protective housing may be obviated. Furthermore, a scale may be integrally moulded with the cartridge wall providing the user with a measure for the medication used and left.

In a most preferred embodiment the cartridge assembly is comprised only of a cartridge being sealed in one end with a sealing, being unitarily moulded with all couplings means and comprising a stopper.

In a cylindrical cartridge the two couplings of the cartridge assembly are generally opposing each other having the same axis. However, the coupling for engaging with the dosing assembly being separate from coupling for engaging the needle assembly may be arranged so that their axis are in any angle with respect to each other, such as perpendicular, or even parallel, but not overlapping.

Another aspect of the present invention is a cartridge being at least partly filled with liquid medication, such as insulin.

In another embodiment the invention relates to a medication delivery device for transferring medication from the cartridge into a syringe with a needle. In this embodiment the coupling means for engaging the needle assembly may be replaced by coupling means for engaging the syringe, or coupling means for both may be provided. The coupling means may be a syringe holder, for example a cylinder coupled to the cartridge comprising a central bore for receiving the syringe. The syringe is coupled to the cartridge having the needle piercing the sealing. By activation of the dosing means the metered amount of medication is driven into the syringe. The syringe is then ready for injection after being removed from the cartridge.

#### DRAWINGS

FIG. 1 is an exploded perspective view of the medication delivery device.

FIG. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use.

FIG. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

#### DETAILED DESCRIPTION OF THE INVENTION

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in FIGS. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.

The dosing assembly 6 is illustrated in FIGS. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances

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axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in FIGS. 1 and 2, and in greater detail in FIG. 3. In FIG. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6. The rod element 7 is adapted to exert an axial movement of the stopper 4 towards the sealed end 22 of the cartridge 5.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

Referring to FIG. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

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The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will cause the stopper 4 to be moved towards the sealed end 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

What is claimed is:

1. A medication delivery device comprising a cartridge assembly having opposite ends and a dosing assembly for setting a desired dose and acting on the cartridge assembly to cause the desired dose to be delivered, wherein:

the cartridge assembly includes a molded cartridge and a stopper disposed in the cartridge, wherein one end of the cartridge assembly is sealed with a pierceable sealing, wherein the one end includes a first coupling means for releasably mounting a needle assembly having a skin-piercing needle, and wherein the other end of the cartridge assembly includes a second coupling means for engaging the dosing assembly, wherein at least one of the coupling means is unitarily molded with the cartridge, and wherein the dosing assembly includes a housing, a plunger, and a mechanism for setting a desired dose and for moving the plunger relative to the housing in an axial direction for administering a set dose, and wherein the dosing assembly housing includes a coupling member for engaging the second coupling means of the cartridge assembly for securing the housing against axial movement relative to the cartridge assembly such that the plunger engages the stopper for moving the stopper in response to the plunger movement wherein the at least one coupling means of the cartridge assembly is a threaded coupling and wherein the second coupling means is an external threaded coupling.

2. The medication delivery device according to claim 1, wherein both said coupling means of said cartridge assembly are unitarily molded with the cartridge.

3. The medication delivery device according to claim 1, wherein the said at least one coupling means of said cartridge assembly is an external coupling.

4. The medication delivery device according to claim 1, wherein the cartridge is molded of a plastic material.

5. The medication delivery device according to claim 4, wherein the cartridge is at least partly transparent.

6. The medication delivery device according to claim 1, wherein the dosing assembly further comprises a scale.

7. The medication delivery device according to claim 1, wherein the coupling means of the cartridge assembly are opposed.

\* \* \* \* \*

# **EXHIBIT 17**



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/348,536	07/07/99	BUCH-RASMUSSEN	5637,200-US

STEVE T ZELSON ESQ  
NOVO NORDISK OF NORTH AMERICA INC  
405 LEXINGTON AVENUE SUITE 6400  
NEW YORK NY 10174-6401

GM12/0117

EXAMINER

SIMMONS, K

ART UNIT

PAPER NUMBER

3763

DATE MAILED:

01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**Application No.  
09/348,536Applicant(s)  
Thomas Bush-Rasmussen et alExaminer  
Kevin C. SirmonsGroup Art Unit  
3763☒ Responsive to communication(s) filed on Oct 27, 2000☒ This action is FINAL.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213.A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133) Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).**Disposition of Claim**☒ Claim(s) 2-7, 10, 12, and 26-28

is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.☒ Claim(s) 2-7, 10, 12, and 26-28 is/are rejected.☐ Claim(s) \_\_\_\_\_ is/are objected to☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been received.☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### DETAILED ACTION

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371 of this title before the invention thereof by the applicant for patent.

2. Claims 26-28, 2-5, 7 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Reynolds U.S. Pat. No. 6,146,361

DiBiasi et al discloses a medication delivery device comprising: a cartridge assembly (22) having opposite ends, and a dosing assembly (38), wherein said cartridge assembly includes a molded cartridge (22) and a stopper disposed in said cartridge (36), wherein one end of said cartridge assembly is sealed with a pierceable sealing (32), wherein said one end includes a first coupling means for releasably mounting a needle assembly having a skin-piercing needle (88), and wherein the other end of said cartridge assembly includes a second coupling means for engaging said dosing assembly (13), wherein at least one of said coupling means is unitarily molded with the cartridge (13, 88), and wherein said dosing assembly includes a housing (38), plunger (distal end of 44), and a mechanism for setting a desired dose and for moving said plunger (col. 3, lines 20-23),

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relative to said housing in an axial direction for administering a set dose (functional language), (fig. 1), and wherein said dosing assembly housing includes a coupling member (41) for engaging said second coupling means of said cartridge assembly (fig. 1); for securing said housing against axial movement relative to said cartridge assembly and such that said plunger engages said stopper for moving said stopper in response to plunger movement (fig 1); wherein both said coupling means of said cartridge assembly are unitarily molded with the cartridge (figs. 1 and 2); wherein the said at least one coupling means of said cartridge assembly is an external coupling (13, 88); wherein the said at least one coupling means of said cartridge assembly is a threaded coupling (13, 88); wherein said second coupling means is an external threaded coupling (13); wherein the coupling of the cartridge assembly are opposed (figs. 1 and 2); wherein the said at least one coupling means is said second coupling means (figs. 1 and 2); wherein said second coupling means is a threaded coupling (figs. 1 and 2); wherein the cartridge is at least partly transparent (figs. 1 and 2).

*Claim Rejections - 35 USC § 103*

3 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4 Claims 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiBiasi et al U.S. Pat. No. 6,146,361 in view of Sams U.S. Pat. No. 4,865,591.

DiBiasi discloses a medication delivery device substantially as claimed except for: wherein the dosing assembly further comprise a scale and wherein the cartridge is molded of a plastic material. However, Sams discloses a dosing assembly with a scale.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cartridge of DiBiasi using the scale as taught by Sams, since Sams discloses that the scale will indicate to the user the amount of dosage selected for injection. Furthermore, it would have been an obvious matter of design choice to mold the cartridge from a plastic material, since applicant has not disclosed that a molded plastic cartridge solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with glass.

*Response to Arguments*

5. Applicant's arguments with respect to claims 2-7, 10, 12, and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

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*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

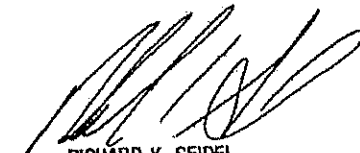
Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Simons whose telephone number is (703)306-5410.

The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

  
Kevin C. Simons

Patent Examiner

1/09/01

  
RICHARD K. SEIDEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700